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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,972	03/01/2002	Robert M. Hoek	DX0936KB	1945

7590 02/02/2005

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EXAMINER	
OUSPENSKI, ILIA I	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,972	HOEK ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2004 and 22 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *2,3,11-15 and 19-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-40, and 16 - 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments, filed 10/14/2004 and 11/22/2004, are acknowledged.

Claims 1 - 20 are pending.

2. Applicant's election of the Invention of Group IV, claims 1, 4 – 10, and 16 – 18, drawn to a method of inhibiting the function of leukocytes in an animal, using an agonist of OX2, where the animal has a neurodegenerative condition, in the reply filed on 10/14/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant further elected the following species:

A. Neural tissue;

B. Multiple sclerosis; and

C. A steroid.

3. Claims 2, 3, 11 – 15, and 19 – 20 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected inventions.

Claims 1, 4 – 10, and 16 – 18 are under consideration in the instant application.

4. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

In addition, Applicant should avoid the use of the word "novel" in the title, as patents are presumed to be novel and unobvious.

6. The abstract of the disclosure is objected to because the first sentence is apparently incomplete. Correction is required. See MPEP § 608.01(b).

7. Applicant's IDS, filed 03/01/2002, is acknowledged, and has been considered.

8. The use of trademarks has been noted in this application (e.g. Zephyr-D on page 21). Each letter of the trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicant is reminded that "BALB/c" is the proper designation of this mouse strain (e.g. page 21 line 6). Appropriate correction is required.

9. Claim 7 is objected to because of the following informalities: in the recitation of "is said agonist," it appears that the intended phrase was "is with said agonist." See also the rejection under 35 U.S.C. 112, second paragraph, below.

Appropriate correction or clarification is required.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1, 4, 5, 7 – 10, 16, and 18 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1, 4, 5, and 16 are indefinite in the recitation of "modulating," because it is ambiguous as to the direction (positive or negative) of said modulating. A skilled artisan would not be reasonably apprised of the metes and bounds of the claimed invention. Applicant is invited to amend the claims to recite "inhibiting" in order to overcome this rejection.

B. Claims 7 – 10 and 18 are indefinite in the recitation of "said administering," because there is insufficient antecedent basis for this limitation in the respective base claims. It appears that "said contacting" was intended.

For examination purposes, the claims will be treated as if they were reciting "said contacting."

C. Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1, 4 – 7, 9 – 10, and 16 – 18 are rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for an agonist of mammalian OX2 protein which is a mammalian OX2 protein, does not reasonably provide enablement for the full breadth of the genus of "agonists" of mammalian OX2 protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification does not provide a sufficient enabling description of the claimed invention.

The specification discloses only a single agonist of OX2, which is the OX2 protein itself, while the instant claims encompass in their breadth any agent that affects the function of OX2.

A person of skill in the art is not enabled to make and use any antagonist of mammalian OX2 commensurate with the scope of the claims as presently recited, because it was well known in the art at the time the invention was made that molecules having highly diverse structural and biochemical properties can function as "agonists." For example, Huang (of record (IDS), see entire document) reviews e.g. on page 202 the daunting task faced by the skilled artisan in developing small molecule regulators of protein function, and notes that the process requires long periods of trial and error testing. The structure of such molecules cannot be readily envisioned by one of skill in the art based upon the guidance provided in the specification as-filed. Therefore, Applicant does not provide a sufficiently enabling disclosure regarding how to make and use OX2 agonists other than the OX2 protein itself.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, the structural features of "agonists"

are unpredictable; thus the experimentation left to those skilled in the art, is unnecessarily, and improperly, extensive and undue.

The scope of the claims must bear a reasonable correlation with the scope of enablement. See In re Fisher, 166 USPQ 18 24 (CCPA 1970). "It is not sufficient to define the recombinant molecule by its principal biological activity, e.g. having protein A activity, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property." Colbert v. Lofdahl, 21 USPQ2d, 1068, 1071 (BPAI 1992).

14. Claims 1, 4 – 7, 9 – 10, and 16 – 18 are rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

Applicant is not in possession of a method of inhibiting the function of leukocytes in an animal using an "agonist" of OX2.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. (See Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column). A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the

genus, one must describe a sufficient variety of species to reflect the variation within the genus. MPEP 2163 II.A.3a.ii.

The claims recite a method of inhibiting the function of leukocytes in an animal using an "agonist" of OX2. However, the specification does not appear to provide a sufficient number of representative species to support a genus of "agonists". The specification discloses only the OX2 protein itself, and mentions "mimetics," e.g. on page 13. These "agonists" lack a common structure essential for their function and the claims do not require any particular structure be shared by the instant "agonists". The genus of "agonists" is thus extremely large, and the specification does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not convey to a person of skill in the art that the Applicant is in possession of the genus of OX2 agonists, commensurate with the scope of the claims as presently recited, because it was well known in the art at the time the invention was made that molecules having highly diverse structural and biochemical properties can modulate signaling in immune cells. For example, Huang (of record (IDS), see entire document) reviews e.g. on page 202 the daunting task faced by the skilled artisan in developing small molecule agents which modulate protein function, and notes that the process requires long periods of trial and error testing. The structure of such agents cannot be readily envisioned by one of skill in the art based upon the written description provided in the specification as-filed.

Thus it does not appear based upon the limited disclosure that Applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the limited number of species disclosed and the extensive variation permitted within the genus of "agonists."

Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 1, 4 – 9, and 16 – 17 are rejected under **35 U.S.C. 102(b)** as being anticipated by Borriello et al. ((WO 97/21450, of record, see entire document).

Borriello et al. teach and claim a method for modulating a T-cell mediated immune response in a subject by administering an OX2 therapeutic agent, such as OX2 protein or OX2 agonist, wherein the subject has e.g. an autoimmune disease (see entire document, in particular, e.g. claims 1, 5, and 6). Borriello et al. further teach that OX2 is involved in activation of T cells (i.e. leukocytes) (e.g. pages 40 – 41, bridging paragraph). Administering OX2 to a subject inherently comprises the step of OX2 contacting any cell type available in said subject, including myeloid lineage cells.

Claims 4 and 5 are included because, even as the elected invention limits the scope of the claims to neurodegenerative condition and neural tissue, respectively, the broad claims as currently recited are anticipated by the reference teachings.

Thus the reference teaching anticipates the claimed invention.

17. Claims 1, 4 – 10, and 16 – 18 are rejected under **35 U.S.C. 102(e)** as being anticipated by Gorczynski (US Patent 6,338,851; see entire document).

Gorczynski teaches a method of preventing or treating an autoimmune disease by administering OX2 protein (see entire document, in particular, e.g. column 2 lines 43 – 49). Gorczynski further teaches that OX2 suppresses immune responses inhibiting IL2 production and generation of cytotoxic T cells (e.g. column 42 first paragraph), i.e. OX2 inhibits activation of T lymphocytes. Since T lymphocytes are leukocytes, it follows that OX2 inhibits activation of leukocytes. Since Gorczynski teaches administering OX2 protein to an animal, the method inherently comprises the step of OX2 contacting any cell type available in said animal, including myeloid lineage cells.

Gorczynski further teaches that autoimmune diseases which can be treated by administering OX2 include multiple sclerosis (column 7 lines 4 – 31). Gorczynski also teaches that pharmaceutical compositions of OX2 protein may additionally contain immunosuppressive drugs (column 10 lines 6 – 24), and exemplifies immunosuppressive drugs by corticosteroids (i.e. steroids) (column 1 lines 39 – 44).

Taken together, these teachings amount to a method of inhibiting activation of a leukocyte in an animal by administering OX2 protein either alone or in combination with steroids, to treat multiple sclerosis, wherein administering OX2 inherently includes contacting myeloid lineage cells.

It is noted that multiple sclerosis is inherently a neurodegenerative disorder, and that its signs or symptoms inherently occur in neural tissue.

Thus the reference teaching anticipates the claimed invention.

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1, 4 – 10, and 16 – 18 are provisionally rejected under the judicially created doctrine of **obviousness-type double patenting** as being unpatentable over claim 1 of copending Application USSN 10/741,430, published as US Pat. Pub. 2004/0213783. Although the conflicting claims are not identical, they are not patentably distinct from each other for reasons set forth herein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 of copending Application USSN 10/741,430 is directed to a method of modulating tolerance to an antigen in a subject with an inflammatory or immune condition or disorder, comprising treating with an agonist or antagonist of CD200 (an alternate art-recognized name of OX2). As tolerance inherently involves trafficking and activation of leukocytes, and administering inherently involves contacting cells within the body, claim 1 of USSN 10/741,430 is not patentably distinct from the instant claimed invention.

Claims 1, 4 – 10, and 16 – 18 are directed to an invention not patentably distinct from claim 1 of commonly assigned Application USSN 10/741,430 for the reasons set forth above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned USSN 10/741,430, discussed above, would form the

basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

20. Conclusion: no claim is allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI
Patent Examiner
Art Unit 1644

January 27, 2005

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1/31/05